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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,627	05/31/2000	JEAN-GERARD GUILLET	97AECNRIMM	7512

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EXAMINER
DECLOUX, AMY M

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/403,627	Guillet et al.
Examiner	**Art Unit**
DeCloux, Amy	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Dec 10, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 21-103 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 21-103 are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. Applicant's submission of the instant application as a 371 is acknowledged, however Claim 1 does not provide a technical feature that is distinguished over the prior art, as evidenced by WO 92 02543 (Feb 1992) which describe novel peptides which bind MHC and which contain a peptide bond that has been replaced by ψ CH2NH for the treatment of autoimmune disease. (See entire article including the Abstract). Therefore, the instant invention lacks Unity of Invention.

2. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 21-34, 65-71, 76-79, drawn to a peptide analog of a parent peptide, and compositions thereof and vaccines thereof, and Claims 61-64, drawn to a method of prevention or treatment of a pathological condition comprising administering a peptide analog,

Group II. Claims 21, 35-38, drawn to a peptide analog which induces the appearance and growth of CTLs and/or induces in vitro cytolysis of target cells, and/or induces the invitro secretion of a cytokine,

Group III. Claims 21, 35-38, drawn to a peptide analog which induces the appearance and growth of CTLs and does not induce in vitro cytolysis of target cells, and does not induce the invitro secretion of a cytokine,

Group IV. Claims 21, 39-48, drawn to a peptide analog wherein the parent peptide is involved in melanoma,

Group V. Claims 21, 49-54, 72-73, 77, drawn to a peptide analog wherein the parent peptide is a peptide of influenza virus, and a vaccine composition thereof,

Group VI. Claims 21, 55-60, 74-75, drawn to a peptide analog wherein the parent peptide is a peptide of the AIDS virus, including wherein the parent peptide is the peptide NEF 84-92 or the peptide GAG 77-85,and a vaccine composition thereof,

Group VII. Claims 80-83, drawn to a complex comprising a peptide analog of a parent peptide,

Group VIII. Claims 84-85, drawn to a method for the in vitro diagnosis of a pathological condition,

Group IX. Claims 86-89, drawn to a kit comprising a peptide analog and a reagent for detecting an MHC-peptide analogue-T cell receptor ternary complex,

Group X. Claims 90-93, drawn to an antibody directed to an antibody directed against a complex consisting of a peptide analog and a component of the MHC, and pharmaceutical compositions thereof,

Group XI. Claims 94-98 drawn to a process for screening peptide analogs

Group XII. Claims 99-103, drawn to a kit comprising molecules of MHC and an antibody directed molecules of the MHC in a conformation which is dependent on binding to the peptide analog.

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-VII, IX-X and XII are unique products. They differ with respect to their structures and physicochemical properties and are therefore patentably distinct.

Groups VIII and XI are unique methods. They differ with respect to ingredients and method steps. a method of making an immunosuppressed animal and a method of preventing disease represent patentably distinct subject matter.

Groups X and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. In the present case, the product as claimed, the antibody can be used in immunopurification.

Groups I and VIII are related as product and process of use. Group VIII involves a second use of the product of Group I (the first use was recited in claims 61-64). Unity of invention permits a product and the first recited use. The second recited use is not the unity of invention.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

For all groups:

a specific peptide analog wherein said analog is specifically defined in its length, in the nature, position and number of each peptide or non peptide bond, and in the nature (in which each and every constituent of each amino acid substitution is defined) and in the position in the peptide analog of each amino acid substitution and in the number of each amino acid substitution in the peptide

a specific animal from which the cell mediated response is mediated

a specific Class I MHC molecule or a specific Class II MHC molecule

For Group I:

a method of either prevention or treatment,

a method comprising a specific pathological condition

a method comprising a specific immune response

For Group II:

a. a specific combination of one or more of the specific properties numbered 1-6,

1) wherein said peptide analog induces the appearance and growth of CTLs in vitro in the presence of factors required for the growth and differentiation of CTLs

2) wherein said peptide analog induces in vitro cytolysis of target cells carrying at the surface of said target cells the peptide analog associated with MHC by means of CTLs,

3)wherein said peptide analog induces in vitro the secretion of a cytokine or an interleukin by means of said CTLs wherein said peptide analog is a TCR agonist, said receptor agonist being derived from the parent peptide which behaves as agonists of said receptors

4)wherein said peptide analog induces in vitro the secretion of a cytokine or an interleukin by means of said CTLs wherein said peptide analog is a TCR agonist, said receptor agonist being derived from the parent peptide which behaves as antagonists of said receptors

5)wherein said peptide analog induces in vitro the secretion of a cytokine or an interleukin by means of said CTLs wherein said peptide analog is a TCR partial agonist, said receptor partial agonist being derived from the parent peptide which behaves as agonists of said receptors

6)wherein said peptide analog induces in vitro the secretion of a cytokine or an interleukin by means of said CTLs wherein said peptide analog is a TCR partial agonist, said receptor partial agonist being derived from the parent peptide which

behaves as agonists of said receptors, the partial agonists inducing the secretion of one or more cytokines other than those whose secretion is induced with the parent peptides,

B. a specific cytokine or interleukin

For Group III

a specific cytokine or interleukin

For Group IV

a specific parent peptide involved in melanoma,

a specific peptide analog such as one recited in claim 42 or claim 48

For Group V

a specific parent peptide involved in influenza virus

a specific peptide analog such as one recited in claim 52 or claim 54

For Group VI

a specific parent peptide of the AIDs virus, such as one recited in claim 56

a specific peptide analog such as one recited in claim 58, 59 or claim 60

For Groups VII or VIII

a complex comprising a specific pathological condition

a complex comprising a specific cell mediated immune response

a complex comprising a specific component of the MHC

a complex comprising a specific TCR

For Group IX

a specific reagent for detecting an MHC-peptide analogue-T cell receptor ternary complex

a specific TCR

For Group X

a specific antibody

For Group XI

a specific first antibody

a specific cell or cell line derived from a specific species

a specific second antibody if applicable, or a specific molecule which itself binds specifically to the molecules of the MHC in said conformation

For Group XII

a specific antibody or a specific molecule which itself binds specifically to the molecules of the MHC in said conformation

a specific control peptide or control peptide analog

The following claim(s) are generic:21-103.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The products, each with a distinct structure and physicochemical properties, are unrelated products are therefore patentably distinct.

The pathological conditions are unrelated disease states. They differ with respect to their etiologies, treatments, prognoses, and sequelae.

Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with *37 C.F.R. § 1.48(b)* if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under *37 C.F.R. § 1.48(b)* and by the fee required under *37 C.F.R. § 1.17(h)*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the

PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
December 17, 2001

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PRIMARY EXAMINER
ART UNIT ~~182~~ 1644